

## **REMARKS/ARGUMENTS**

Reconsideration and allowance of this application and the amended claims therein are respectfully requested. Upon entry of the foregoing amendment, claims 3, 22-24, and 39-73 have been canceled. Claims 1, 2, 4-21, and 25-38 are pending.

Claims 1, 4, and 25-27 are amended herein. Support for the amendment to claim 1 is found in paragraph [0093] of the application as filed. Claims 1, 25, and 26 were also amended for reasons related to establishing or clarifying antecedent basis, and these amended claims are fully supported by the original specification and claims as filed. The amendments to claims 4 and 27 are supported by original claims 4 and 27 and by paragraph [0046].

### **1. Rejections**

#### **A. 35 U.S.C. § 101**

The Office Action rejects claims 1-2, 4-22, and 24-38 under 35 U.S.C. § 101 for alleged lack of either a specific asserted utility or a well-established utility. Applicants respectfully submit that this rejection should be withdrawn for all pending claims because the Office Action does not establish a *prima facie* case of lack of utility. Furthermore, as demonstrated herein, even if a *prima facie* case of lack of utility had been established in the Office Action, Applicants are able to rebut it.

Applicants repeat all of their previous arguments directed to the Office's failure to establish a *prima facie* case of lack of utility as well as Applicants' rebuttal of such a case if it were established. The Office Action does not establish a *prima facie* case of lack of utility, because it does not consider all of the asserted utilities in the application. Even if the Office Action did establish a *prima facie* case of lack of utility, such a *prima facie* case would be overcome by the specific and substantial utilities presented in the application.

The Examiner's attention is drawn to the recent decision of the United States Court of Appeals for the Federal Circuit in In re Fisher (04-1465, Serial No. 09/619,643, decided Sept. 7, 2005). In Fisher, the court defined the disclosure necessary to satisfy both the "substantial" utility requirement and the "specific" utility requirement. "Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public. Turning to the 'specific' utility requirement, an application must disclose a use which is not so vague as to be meaningless." In re Fisher, at \*10.

Unlike the ESTs of Fisher, the isolated polynucleotides claimed in this invention have both specific and substantial utility. The accepted commercial utility of increased transcription of a promoted polynucleotide is well-established and substantial. Operation of the claimed regulator in *Corynebacteria*, particularly with respect to the polynucleotides set forth in the dependent claims, is a definite, specific utility.

In addition, the Applicants respectfully submit that the Office has too quickly dismissed the valuable insight provided by the  $\beta$ -galactosidase activity as disclosed in the application. As would be readily recognized by one skilled in the art, the  $\beta$ -galactosidase activity is indicative of the regulator activity described and claimed in the application. This activity alone would be sufficient to demonstrate utility of the claimed invention, but when viewed in light of the other arguments presented in prior responses (and incorporated by reference herein), that evidence is particularly persuasive.

#### **B. 35 U.S.C. § 112**

The Office Action rejects claims 1-38 under 35 U.S.C. § 112, first paragraph, for alleged failure to show a person skilled in the art how to make and use the invention. The Office Action

states that the rejection is based on the alleged lack of "either a specific asserted utility or a well established utility for the reasons set forth [in the rejection based on 35 U.S.C. § 101]. . . ."

This rejection is based on the 35 U.S.C. § 101 rejection appearing in this Office Action. As set forth above, that rejection should be withdrawn for failure to establish a *prima facie* case of lack of utility. Because the rejection under § 101 fails, this rejection must necessarily fail as well for all claims that remain pending.

The Office Action also rejects claims 1-38 under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. The Advisory Action indicated that this rejection was overcome by the reply after the final rejection for the claims that remained following the proposed amendment. The amendments included in that reply have been repeated in this Submission, and the arguments for traversal of the rejection that were presented in that reply are repeated as if fully rewritten herein. The Examiner is thanked for indicating that this rejection has been overcome for the amended claims.

Applicants respectfully submit that the requirements of 35 U.S.C. § 112 have been satisfied by all pending claims of the application as amended herein. Withdrawal of the rejections and allowance of the pending claims is respectfully requested.

### **C. 35 U.S.C. § 102**

As noted in the Advisory Action, the rejection of claim 24 under 35 U.S.C. § 102 has been rendered moot by the cancellation of claim 24.

## **2. Conclusion**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all of the outstanding objections and rejections, and then allow all of the

outstanding claims as amended. Applicants believe that a full and complete reply has been made to the Office Action and that the application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite allowance of this application, the Examiner is invited to telephone the undersigned at the number provided.

**Authorization**

It is believed that this Submission is timely with payment of the fee for the included Petition for Extension of Time, and that no additional fees or extensions are necessary. If an extension of time and/or additional fee is necessary to make this response timely, please deduct the fee for same from deposit account 02-4553, in the name of Buchanan Ingersoll PC.

Respectfully submitted,



Duane A. Stewart III  
Registration No. 54,468  
BUCHANAN INGERSOLL PC  
One Oxford Centre  
301 Grant Street  
Pittsburgh, Pennsylvania 15219  
Attorneys for Assignee of Entire Interest  
ph: (412) 562-1622  
fx: (412) 562-1041

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